EXHIBIT B

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

Andrew G. Finkelstein
Finkelstein and Partners
436 Robinson Avenue
Newburgh, NY 12550

APR 12 2005

Re: Neurontin

Dear Mr. Finkelstein:

This is in response to your letter dated March 21, 2005, which raises several questions about the relationship between treatment with Neurontin and suicide. With the letter, you provided 258 MedWatch forms of patients whom you state committed suicide while being treated with Neurontin, and you make several allegations about FDA's handling of this matter. Your letter references the Citizen Petition you submitted on May 17, 2004, requesting that FDA require Pfizer Inc, the manufacturer of Neurontin, to amend the drug labeling to warn prescribers and health care professionals of the escalating numbers of postmarketing safety reports of completed suicides by patients treated with Neurontin for both its labeled and unlabeled indications. Because you indicated that you wanted to maintain your clients' confidentiality with regard to the data regarding suicides that you compiled in connection with litigation, your citizen petition was supported only by adverse event reports (AERs) you obtained from FDA's spontaneous reporting system under the Freedom of Information Act. I will address the matter of these data later in this response.

First, let me assure you that we are taking this matter very seriously, and have given it a great deal of attention since you first contacted us about it. As your March 21 letter states, we sent you an interim response to your citizen petition, as provided by our regulations, on November 5, 2004. We are currently in the process of reviewing your Citizen Petition. Our response will be based on the data and information submitted with the Citizen Petition, as well as data available to us in the new drug application (NDA) for Neurontin, and other data from our postmarketing surveillance system. However, given that you have now submitted MedWatch forms for 258 individuals, and that those reports are clearly relevant to the issues raised by your citizen petition, we believe that we cannot fully respond to your petition without considering those reports. Unfortunately, our review of those reports will take some time, not only because of the need to ascertain which are duplicative of reports already reported to MedWatch but because of the need to carefully investigate the facts of each report.

In our conversation with you of March 14, 2004, you indicated that the vast majority of patients in your database who committed suicide were receiving treatment with Neurontin for psychiatric illnesses. We noted at that time that these illnesses are well-known to be associated with an increased risk of suicide compared to the general population. Further, in the absence of an appropriate control group, it will be difficult, if not impossible, to assess the role of any other factors that might explain these events, such as concomitant medications. For these reasons, we

urged you to engage the services of an expert to help you analyze and interpret this data; as far as we know, you have not done this. Nevertheless, we intend to make every effort to fully understand the implications of the data you have supplied to us.

You mention that FDA has not actively pursued Parke-Davis for the off-label promotion of Neurontin. We disagree with your allegation that FDA has been inactive in protecting the health and safety of the American public with respect to the off-label promotion of this drug product. FDA investigated this matter and worked closely with the Department of Justice in prosecuting the company for these marketing practices. Your letter recognizes that the prosecution was successful, resulting in a guilty plea and a substantial fine by the company.

Your letter described particular concerns about the evidence for Neurontin-induced suicidal behavior in the data submitted in the NDA, as reflected in the review of that NDA performed by Dr. Cynthia McCormick. We will address those issues in our response to your Citizen Petition even though the petition itself did not raise them.

We would also like you to know that in part because of the concerns you have raised, we have asked the sponsors of all drugs approved to treat epilepsy to re-analyze their controlled trials databases to examine the question of drug-induced suicide and/or suicidality. These analyses will be similar to the detailed analyses that were recently performed to evaluate the question of whether or not antidepressant drugs increase these events in pediatric patients. As you undoubtedly know, these analyses are complex, and will require a detailed re-examination of all adverse events that could possibly be related to the events of interest, and a blinded re-categorization of these events into relevant categories. We believe that these analyses are crucial to deciding the obviously important question of whether or not these drugs do increase the risk of suicidality.

Again, I apologize for the length of time it has taken us to complete our analysis of your Citizen Petition. I can assure you that you will receive a response, as soon as we thoroughly review the data you have most recently provided to us. In particular, we will address your requests for specific changes to the Neurontin label.

Sincerely,

Russell Katz, M.D.
Director
Division of Neuropharmacological Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research